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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/476,202	01/03/2000	JOHN D. NOTI	052544-0108	7459

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FOLEY & LARDNER
150 EAST GILMAN STREET
P.O. BOX 1497
MADISON, WI 53701-1497

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary**Application No.**

09/476,202

Applicant(s)

NOTI, JOHN D.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003 and 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 18-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,11-13,15 and 17 is/are rejected.
- 7) ☒ Claim(s) 2,8-10,14 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-43 are pending. Claims 18-43 are withdrawn from consideration. Claims 1-17 are under consideration.

Election/Restrictions

The restriction requirement was made final in the prior Office action mailed 03 December 2002. According to 37 CFR 1.144, Applicant may petition the restriction requirement made final in the prior Office action on the merits:

After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181).

Response to Amendment

Claims 1, 3-7, 11-13, 15 and 17 stand rejected under 35 U.S.C. 112, first paragraph.

The rejection of the claims under 35 U.S.C. 112, second paragraph have been withdrawn in view of Applicant's amendments.

Response to Arguments

Claims 1, 3-7, 11-13, 15 and 17 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

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Applicant argues that the written description requirement has been met because:

Example 1 describes the identification of the promoter, example 2 describes the isolation and sequence analysis of 'the 5' flanking region, example 3 describes the determination of the transcription CD11d start site of the CD11d gene, example 4 describes the functional analysis of the CD11d promoter including the identification of several sequences that include the sequence that provides the promoter activity, example 5 describes the interaction of DNA binding proteins with the CD11d sequence, example 6 describes sequence deletions that reduce activity of the promoter, example 7 regulation of the CD11d promoter region, and example 8 describes myeloid-specific down regulation of CD11d by PMA.

Although Applicant's disclosure teaches the elucidation of the promoter and in particular sequences in the promoter related to activity, it fails to provide written description for the broad genus claimed. The instant claims are drawn to sequences all or a functional portion of a promoter which includes one or more modifications such that the ability to direct myeloid cell specific expression is maintained, which may further comprise various modifications. It remains unclear what the functional portions and what modification can be made such that myeloid specific promoter activity can be maintained. The modifications recited in the claim embrace modifications anywhere within the promoter region including inside the cis-acting elements such that it is unknown what sequences embraced by the claim will result in functional activity. Moreover, the sequences embraced by broad language such as the language in claim 1 read on any fragments or portions of the CD11d gene promoter which represents a wide array of molecules. Therefore, the invention is not described in such full, clear and concise language as to indicate that Applicant was in possession of the invention.

Allowable Subject Matter

Claims 2, 8-10, 14 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636



JAMES KETTER
PRIMARY EXAMINER